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Date: February 2022

RE: Dr. Brown's Medical Letter of Validation to Support Steam Sterilization (Autoclaving)

Please find the below information addresses all inquiries regarding the effectiveness of Steam Sterilization (Autoclaving) to eradicate microorganisms when used with Dr. Brown's® bottle system (vessel, insert, reservoir, nipple, collar, and cap*). The testing was coordinated at an FDA registered; third- party accredited to ISO 17025 standards laboratory – Nelson Laboratories in Salt Lake City, Utah. The decontamination final report revealed >/= to 99.99% eradication of a highly moist-heat resistant microbe (Geobacillus stearothermophilus) when used according to normal steam sterilization and drying guidelines.

The mechanisms for obtaining the results were the following:

1. Test method acceptance criteria was performed in accordance with the guidance document for a total of 30 cycles.

2. Protocol was in line with all decontamination protocols including the guidelines for use with normal steam sterilization (autoclaving) process.

Steam Sterilization Repeat Exposure Testing Set Points

Sterilizer Type	Pre-Vacuum
Preconditioning Pulses	3
Temperature	132°C
Full Cycle Exposure Time	04 minutes 00 seconds
Dry Time	30 minutes 00 seconds
Test Article Configuration	Individually single pouch each test article and place on edge in sterilizer

3. Calculations for the reduction in bacterial counts were calculated using the following formula:

% Reduction = 100 – (Final Population/Initial Population x 100)

*Autoclave (Steam Sterilization) is recommended not to exceed 30 cycles and is NOT recommended for the Infant-Paced Feeding Valve (blue one-way valve), Non-Metal Brush or AccuBrush™.

Thank you for allowing us the opportunity to share our findings with you. We are very proud of our products and the outcome of this testing. We look forward to conducting business with you and your institution.

Sincerely,

Sandra J. Aubuchon

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